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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/013,980	11/05/2001	Gust H. Bardy	032580.0060.CIP	3720

28075 7590 05/05/2004

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

9

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/013,980

Applicant(s)

BARDY ET AL.

Examiner

Kennedy Schaetzle

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the examiner cannot find a reference in the specification relating to the surface area of the lead electrode extending to 5000 square mm (see for example claim 9).

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-8, 18-25, 35-42 and 52-56 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8, 61-68, 81-85, 121-128, and 181-188, of copending Application No. 09/941,814. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

It should be noted that claims directed to the amount of effective energy applied do nothing to limit the apparatus and therefore are considered identical from an apparatus standpoint.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 9-17, 26-34, 43-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-25, 81-85, 141-145 and 201-205 of copending Application No. 09/941,814. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application claims are merely broader than the copending application's claims (e.g., the recited range of 100-5000 square millimeters covers all of the possible square areas claimed in the '814 application). If the applicant receives a patent on the more specific embodiment, he is not entitled to a patent for the generic or broader invention (see *In re Goodman*, 11 F. 3d 1046, 29 USPQ 2d 2010 (Fed. Cir. 1993)). Regarding claims 57 and 58, note the comments below regarding claim interpretation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-9, 13, 14, 35-43, 47, 48, 52-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahl et al. (Pat. No. 5,020,544).

Regarding claim 1 and claims with similar limitations, Dahl et al. disclose a lead electrode assembly for use with an implantable cardioverter-defibrillator 28 comprising an electrode 10. While the intended use (i.e., for subcutaneous placement between the third and twelfth ribs) for the cardioverter-defibrillator was considered, such statements fail to saliently distinguish over the apparatus of the prior art. In fact, claim 1 is so broadly drafted that it encompasses literally every lead electrode assembly ever patented.

Regarding claims directed to the effective energy for shocking, practically any energy level can be considered effective to shock the heart. The applicant is not claiming that the shock need effectively revert any fibrillation event –merely that it be sufficient to effectively shock the heart. In any event, the electrode of Dahl et al. is capable of emitting whatever energy is applied to it. The applicant is not claiming any shock generation structure, but simply a lead assembly for use with an implantable cardioverter-defibrillator. Furthermore, since the actual energy required to effect defibrillation or cardioversion greatly varies depending on a host of patient specific factors (e.g., size and weight of patient, heart condition, age, etc.), as well as electrode location, pulse morphology, etc., recitations attempting to limit the apparatus by restricting the amount of energy applied to it, fail to distinguish over the prior art of record.

Regarding claims 9, 13, 14 and claims with identical limitations, note col. 5, lines 56-68.

Concerning claims 52-56, recitations regarding the location of structure with respect to the body will have no effect in overcoming the prior art of record.

Patentability resides with the structure of the device and not where the device happens to be located.

Regarding claims 57 and 58, no structure or means have been recited to bring about the desired outcome of providing anti-tachycardia pacing energy to the heart for the treatment of atrial fibrillation or ventricular tachycardia. The applicant does not appear to be claiming a step in a method, and therefore a recitation of structure is required if it is to distinguish over the apparatus of Dahl et al..

8. Claims 18-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Heil et al. (Pat. No. 6,256,541).

Regarding claim 18, Heil et al. disclose an implantable cardioverter-defibrillator comprising a housing 210, an electrical circuit located within the housing (see second paragraph of col. 11), a first electrode coupled to the electrical circuit and located on the housing (note the third full paragraph of col. 12), and a lead electrode assembly 24 coupled to the housing comprising a second electrode (either electrode 40 or 44) coupled to the electrical circuit.

The recited intended use in the claim preamble was considered, but deemed insufficient to saliently distinguish over the prior art of record.

Regarding claims directed to the amount of shocking energy, note the rejection of related claims above. Similar arguments apply here as well.

9. Claims 1-10, 18-27, 35-44 and 52-56 rejected under 35 U.S.C. 102(e) as being anticipated by Schloss (Pat. No. 6,539,260).

Comments made above concerning intended use and the amount of shocking energy apply here as well.

Regarding claim 1, Schloss discloses a lead electrode assembly with an electrode 150.

Regarding claims 18 and 35, see Fig. 1.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 10-12, 15-17, 44-46 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahl et al. (Pat. No. 5,020,544).

Although Dahl et al. do not explicitly discuss the recited ranges of surface area, the applicant gives no criticality whatsoever to the exact surface area employed in the construction of the electrode device. Lacking any criticality or advantage in one range over another, it would appear that the device of Dahl et al. which sets forth a surface area of 3000 square millimeters, thus landing it solidly within the general broad range recited by the applicant (i.e., 100-5000 square millimeters), would by default perform equally as well. Those of ordinary skill in the lead electrode art would have therefore considered the various modifications in surface area to be a matter of obvious design dependent upon the particular application at hand and a host of patient-defined parameters.

12. Claims 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heil et al. (Pat. No. 6,256,541).

A related argument to that made in the rejection set forth in paragraph 8 of the present Office Action applies here as well. In this case, Heil et al. teach that the second electrode (i.e., the defibrillation electrodes) may be in the range of 200-1000 square millimeters –again within the range recited by the applicant.

13. Claims 11-17, 28-34, 45-51, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schloss.

A related argument to that made in the rejection set forth in paragraph 8 of the present Office Action applies here as well. In this case, Schloss teaches that the second electrode (i.e., the defibrillation electrode 150) may be in the range of 60-1000 square millimeters or more –again within the range recited by the applicant.

14. Claims 57 and 58 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schloss.

The examiner considers Schloss to anticipate claims 57 and 58 for the same reason argued above in the rejection of said claims under Dahl et al.. In any event, Schloss discloses pacing structure in both the atrium and the ventricle for applying remedial pacing therapy such as anti-tachycardia pacing (note the text abridging cols. 5 and 6). Since it is old and well-known by any artisan of ordinary competence in the field of electrical therapy that atrial fibrillation and ventricular tachycardia may be reverted with pacing energy (or in the very least that it would be obvious to first try pacing in a tiered therapy approach to combat such arrhythmias before attempting more severe measures such as cardioversion or defibrillation), the employment of such structure to apply anti-arrhythmia pacing to the chamber in need of such pacing would have been considered obvious by those of ordinary skill in the art.

Conclusion

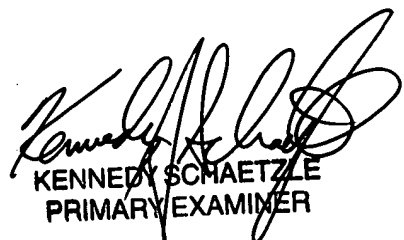
15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
April 10, 2004


KENNEDY SCHAETZLE
PRIMARY EXAMINER